

REMARKS/ARGUMENTS

Claims 1-4 are pending in the application. A minor amendment has been made to claim 1. The amendment is supported by the application as originally filed and is not believed to raise any issue of new matter. The amendment to claim 1 is made for the purpose of clarification and it is not believed to affect the scope of the originally filed claim. Entry of the claim amendment is respectfully requested.

Objection to the Specification

On p. 3 of the Office Action the Examiner requests that the specification be amended to add the section heading "Brief Description of the Several Views of the Drawings".

In response, applicant submits that the requested amendment is presented above and that the amendment is believed to overcome the Examiner's objection.

Claim Rejections Under 35 U.S.C. §112

Claim 1 is rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. The Office Action states that, "It is unclear if the ingredients in claim 1 read on "hydroxyethylcellulose ; bioadhesive agent; glycerol . . ." or "hydroxyethylcellulose; glycerol" as disclosed in the specification on p. 2, lines 17-27.

In response, applicant submits that the latter interpretation is correct, i.e., hydroxyethylcellulose is the only gelling agent and bioadhesive agent. Claim 1 has thus been amended to reflect the above-described state of affairs and to ensure correspondence with the teaching(s) contained in the written description of the invention contained in the specification as filed.

The Examiner goes on to state, at p. 3 of the Action, that, "It is unclear what the term 'gelling agents' encompass. From the disclosure 'gelling agents' encompass only hydroxyethylcellulose, acrylic or methacrylic acid polymers, chitosan and polycarbophil."

In response, applicant respectfully submits that one having an ordinary level of skill in the relevant art would be well acquainted with the concept of "gelling agents" and well aware of what materials constitute such 'gelling agents'. The particular materials referred to in the Office

Action, as discussed for example at p. 1 of the specification, are provided as non-limiting examples of gelling agents that are well known and commonly used in this art.

Based on the remarks presented above, the Examiner is respectfully requested to reconsider and withdraw the rejections of applicant's claims under §112, second paragraph.

Claim Rejections Under 35 U.S.C. §102

Claims 1, 3 and 4 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Published U.S. Patent Application No. 2003/0039704 A1 of Arkin et al. ("Arkin"). The rejection is respectfully traversed.

Applicant's independent claim 1 is directed to a composition in the form of an aqueous bioadhesive gel adapted for delivery of at least one of active ingredients and principles. As presently amended the claim recites that the subject composition comprises: (1) hydroxyethylcellulose as the only gelling agent and bioadhesive agent; (2) glycerol; (3) diethylene glycol monoethyl ether; and at least one (4) surfactant, preservative and acidifier.

In contrast, the Arkin reference discloses, in examples 1-4 gel compositions comprising hydroxyethylcellulose, diethylene glycol monoethyl ether, surfactants and preservatives, but **not acidifiers**. The reference does mention acidifiers, but only in the context of Examples 5 and 6 which are directed to creams (not gels) comprising lactic acid. These cream compositions, however, contain **no hydroxyethylcellulose**, i.e., because they are **not gels**.

Thus, the reference does **not** disclose compositions comprising hydroxyethylcellulose **and** an acidifying agent. Rather, it discloses (1) gel compositions comprising, *inter alia*, hydroxyethylcellulose, and (2) cream compositions comprising, *inter alia*, an acidifier (e.g., lactic acid). There is **no** teaching, however, or even a suggestion, of a composition comprising **both** the hydroxyethylcellulose and an acidifier.

Since, therefore, the reference does not disclose any composition including all of the claimed constituents recited in, e.g., claim 1, applicant respectfully submits that claim 1 is **not anticipated** by the Arkin reference. The Examiner is, thus, respectfully requested to reconsider and withdraw the rejection under 35 U.S.C. §102(b) of claim 1. Moreover, claims 3 and 4 each depend, directly or indirectly, from claim 1 and thus these claims include all of the features

recited in claim 1. Therefore, claims 3 and 4 are also believed to overcome the anticipation rejection for the same reasons as claim 1. The Examiner should also, therefore, withdraw the §102(b) rejection of claims 3 and 4, together with that of claim 1.

Further to the above, on pp. 4-5 of the Office Action claims 1-4 are rejected under 35 U.S.C. §103 as being allegedly “obvious” over the Arkin reference. This rejection is also respectfully traversed.

As indicated above in the discussion of the rejection under 35 U.S.C. 102(b), the Arkin reference does not disclose any composition comprising both hydroxyethylcellulose and an acidifier. Rather, the reference separately discloses (1) gel compositions comprising hydroxyethylcellulose and no acidifier and (2) cream compositions comprising lactic acid as an acidifier but no hydroxyethylcellulose. The Examiner has not pointed to, nor is applicant aware of any, teaching or suggestion to modify the “gel” composition(s) described by the subject reference to include an acidifier or to modify the “cream” composition(s) to include a gel-forming hydroxyethylcellulose component. Thus, applicant respectfully submits that the reference does not in any way suggest the composition recited in, e.g., claim 1 since it contains no teaching, or even a suggestion, to combine a hydroxyethylcellulose and an acidifier in the same composition, which is what is presently claimed by applicant.

Claim 1, therefore, is believed to be non-obvious over the disclosure contained in Arkin. Furthermore, claims 2-4 are also distinguishable over the cited reference since, due to their dependence upon claim 1, they contain all of the recitations of that claim and, thus, are distinguishable for the same reason(s) as claim 1. The Examiner should therefore reconsider and withdraw the rejection of applicant’s claims 1-4 under 35 U.S.C. §103.

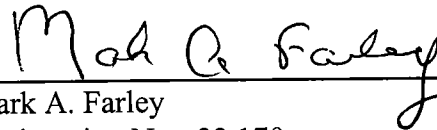
Summary

Based on the claim amendments and remarks presented herein, the Examiner is respectfully requested to reconsider and withdraw all of the objections and rejections of this application that are set forth in the pending Office Action issued in this case and to issue a Notice of Allowance. If the Examiner does not agree that the case is in condition for an allowance, if he believes an interview would advance the prosecution of this application, he is respectfully invited

to telephone applicant's representative at the number below in order that such an interview may be arranged in an effort to overcome any remaining impediments to an allowance of the application.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Mark A. Farley", is written over a horizontal line.

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